510(K) SUMMARY

MAY 3 1 2006

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(K) number is: K060352

Device Name:

Proprietary Name: Health Line International Corporation's IV Administration and Extension Sets

Common/Usual Name: Intravascular Administration Sets

Classification:

Class II:	Per 21 CFR 880.5440
Panel Number:	Panel 88
Product Code:	FPA

Predicate Device:

The HLIC IV Administration Sets are substantially equivalent to Baxter K925126 and the HLIC Extension Sets are substantially equivalent to Baxter K89098 Predicate Devices.

Device Description:

HLIC's IV Administration Sets covered by this submission are gravity feed Intravascular Administration Sets. They are to be used for administering fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein.

Intended Use

The intended use of health Line International Corporation's IV Administration Sets and Extensions Sets is for the safe and effective administration of fluids from a container to the patents vascular system and/or to draw blood from the patient's vascular system. Product is DEHP free for use on all patient populationsThe technical characteristics of HLIC's IV Administration Sets and Extension Sets and Baxter's predicate device are substantially equivalent. HLIC's spike dimensions are slightly different from Baxter's predicate devices. HLIC's spike length is more compliant to ISO 8536-4:2004 dimensions than Baxter's predicate devices.
The performance data and the safety data indicated that HLIC's devices are substantially equivalent to Baxter's IV Administration Sets, Extension Sets. And McGaw (B. Braun Needle Free Injection Site Caps. HLIC's devices were all compliant with ISO 8536-4:2004 and ISO 10993 requirements.

Conclusion:

K060352

The following conclusions can be drawn from reviewing the safety and efficacy data of the 510(K) and physical dimensional data all indicated that HLIC's IV Administration Sets and Extension Sets are substantially equivalent to Baxter's predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2006

Mr. Jack Speer, MS, RAC
V.P. Business Development and Regulatory
Health Line International Corporation
Freeport Center Building E-13 Drive 21
P.O. Box 160435
Clearfield, Utah 84016-0435

Re: K060352
Trade/Device Name: IV Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: May 11, 2006
Received: May 12, 2006

Dear Mr. Speer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(K) Number (K060352)
Device Name: IV Administration Set

Indication for Use:

The indicated use of health Line International Corporation's IV Administration Sets and Extensions Sets is for administration of fluids from a container to the patents vascular system.

(Signature of Verifier)

Jack R. Speer

May 11, 2006

Prescription Use: Yes X AND/OR Over The Counter Use No
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(510(k) Number: K060352